

# Notice of Allowability

Application No.

09/463,470

Examiner

David A Saunders, PhD

Applicant(s)

SOEGAARD ET AL.

Art Unit

1644

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment and 1.132 declaration filed 8/31/04.

2. ☒ The allowed claim(s) is/are 35-46.

3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some\* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_

4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_

7. ☒ Examiner's Amendment/Comment

8. ☐ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_.

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- 1) The amendment of 8/31/04 and 1.132 declaration executed by Goran Forseberg have been entered. Claims 35-46 are pending and allowed.
- 2) The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The filing date of provisional application 60/053211 on the Application Data Sheet filed 11/11/02 (where the claim for priority is listed in lieu of the oath/declaration) is in error. The correct date is 07/21/97, not 07/11/07.

- 3) An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Fox on 9/27/04.

Appearing below is a complete listing of the claims and the status of each, as of the amendment of 8/31/04.

Claims 1-34 (Canceled).

35. (Previously presented) A method for inactivating a target cell in the presence of T cells comprising bringing the target cell and a T cell in contact with a superantigen in the presence of an immune modulator wherein at least one of the superantigen and immune modulator is conjugated to a targeting moiety that targets the target cell.
36. (Previously presented) The method of claim 35, wherein the superantigen and immune modulator are both conjugated to the same targeting moiety, the conjugate being a triple conjugate.
37. (Previously presented) The method of claim 35, wherein the superantigen and targeting moiety are conjugated.
38. (Previously presented) The method of claim 37, wherein the immune modulator is not conjugated to the targeting moiety.
39. (Previously presented) The method of claim 35, wherein the target cell is inactivated in vivo in an individual having a disease associated with the target cell.
40. (Previously presented) The method of claim 39, wherein the disease is cancer.
41. (Previously presented) The method of claim 35, wherein the targeting moiety is selected from the group consisting of an antibody, an antigen-binding fragment of an antibody, an Fab fragment of an antibody, an Fab<sub>2</sub> fragment of an antibody, or a single chain antibody.
42. (Previously presented) The method of claim 35, wherein the superantigen is modified to have a decreased ability to bind to MHC class II antigen compared to the corresponding wild type superantigen.
43. (Previously presented) The method of claim 35, wherein the superantigen is modified to have decreased seroreactivity in human sera compared to the corresponding wild type superantigen.

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44. (Previously presented) The method of claim 35, wherein the superantigen is chimeric comprising sequences derived from two or more wild type superantigens.

45. (Previously presented) The method of claim 35, wherein the immune modulator is selected from the group consisting of cytokines, chemokines, and extracellular parts of lymphocyte bound receptors and ligands.

46. (Previously presented) The method of claim 35, where in the immune modulator is IL-2.

Claims 47-84. (Cancelled)

4) Any inquiry concerning this communication from the examiner should be directed to David A Saunders, PhD whose telephone number is 571-272-0849.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*David A Saunders*

DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182

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